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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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| APPLICANT: | UNIVERSITY OF UTAH RESEARCH |) |
| | FOUNDATION |) |
| | |) |
| INT. APP. NO: | PCT/US98/20046 |) |
| | |) |
| FILED: | 23 SEPTEMBER 1998 |) |
| | |) |
| PRIORITY: | 23 SEPTEMBER 1997 |) |
| | |) |
| TITLE: | ACOUSTICALLY ACTIVATED |) |
| | LOCALIZED DRUG DELIVERY |) |
| | |) |
| FILE REF: | T5986.PCT |) |
| | |) |

RESPONSE UNDER
RULE 66.3

Assistant Commissioner for Patents
Box PCT
Washington, D.C., 20231

Dear Sir:

This communication is in response to the PCT Written Opinion (PCT Rule 66) mailed September 13, 1999.

Enclosed herewith are substitute sheets numbered pages 2, 10-12, 14, 16-18, 20, and 24-26 for amending the description of the invention. At page 2, line 5, the Kabanov reference was deleted. At page 10, line 17, the term "or 16-DS" was added to indicate another term well known in the art for 16-doxyl stearic acid. At page 10, line 26, a sentence was deleted. At page 11, line 28, the words "the antioxidant" was deleted. At page 11, line 31, the words "or doxorubicin" were added before the word "absorbed." At page 12, line 15, the Stern-Volmer equation was corrected. At page 12, line 20, "for" was substituted for "of." At page 12, line 29, the word "only" was deleted. At page 14, line 25, a typographical error in the spelling of "as" was corrected. At page 16, line 28, a sentence was deleted. At page

17, lines 5-6, the first sentence was amended in agreement with the remainder of the paragraph. At page 17, line 16, the word "young" was inserted. At page 17, line 28, the word "however" was inserted. At page 18, line 7, "taken" was substituted for "take." At page 20, line 11, a paragraph was deleted. At page 24, line 5, the words "by photon correlation spectroscopy" were deleted. At page 25, line 4, the words following "doxorubicin" were deleted. At page 25, line 8, a typographical error in the spelling of "with" was corrected. At page 25, line 26, the word "somewhat" was inserted. At page 26, line 30, the "shown" was substituted for "should."

Also enclosed herewith are substitute sheets numbered pages 30-32 for amending the claims and replacing original sheets 30-31. The independent method claims, i.e., claims 1, 16, and 24, were amended by deleting the phrase "the steps of" from the preambles thereof. Original claim 13 was been deleted and the subject matter thereof incorporated into claim 9. Therefore, claims 13-24 as amended correspond to claims 14-25 as originally filed. New claims 25-31, which are analogous to claims 2-8, were added as dependent claims to claim 24.

In the reasoned statement under Rule 66.2(a)(ii) of the Written Opinion, it was alleged that claims 9-16 lack novelty and inventive step. More particularly, it was alleged that claims 9-16 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,698,529 (hereinafter, "Alakhov"), and that claims 9-11 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 4,182,330 (hereinafter, "Michaels").

Before discussing these allegations, it is believed proper to state the legal basis underlying novelty under the PCT Articles and Rules. PCT Article 33(2) states: "For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations." PCT Rule 64.1(a) states that: "For the purposes of Article 33(2) and (3), everything made

available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) shall be considered prior art provided that such making available occurred prior to the relevant date." As set forth in PCT Rule 64.1(b), such relevant date is the earlier of the international filing date and the priority date of an earlier application where a valid priority claim has been made.

Further, PCT Rule 64.3 states in pertinent part (emphasis added):

In cases where any application or any patent which would constitute prior art for the purposes of Article 33(2) and (3) had it been published prior to the relevant date referred to in Rule 64.1 was published on a date which is the same as, or later than, the relevant date but was filed earlier than the relevant date or claimed the priority of an earlier application which had been filed prior to the relevant date, such published application or patent shall not be considered part of the prior art for the purposes of Article 33(2) and (3).

The present application has an international filing date of September 23, 1998, and claims priority to earlier U.S. Application No. 60/059,774 filed September 23 1997. Alakhov issued as a U.S. Patent and became available to the public on December 16, 1997. Therefore, under Rules 64.1 and 64.3, Alakhov is not prior art to the instant application because Alakhov became available to the public after the priority date of the present application. Since Alakhov is not prior art, the allegation that the present application is anticipated by and lacks novelty in view of Alakhov is erroneous and should be withdrawn. Applicants therefore respectfully request that the international preliminary examination report be established to reflect this fact.

With respect to the allegation that claims 9-11 and anticipated and lack novelty in view of Michaels, it is respectfully submitted that anticipation under the PCT requires that each and every element of the claimed invention be disclosed

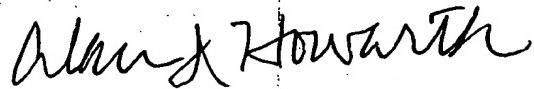
in a single prior art reference. Stated another way, a party asserting anticipation of a patent claim must demonstrate, among other things, identity of invention. It is further respectfully submitted that the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.

Claim 9 has been amended by incorporating the subject matter of original claim 13, i.e., that the drug is hydrophobic. As recognized by the Examiner in the Written Opinion, Michaels fails to disclose a composition comprising a micellar drug carrier and a hydrophobic drug. Michaels relates only to delivery of amphipathic drugs. Therefore, it is respectfully submitted that Michaels fails anticipate the invention of claims 9-11, and withdrawal of the allegation that novelty is lacking is respectfully requested.

For the reasons given above, it is respectfully submitted that none of the subject matter presently claimed is anticipated by the cited references. It is respectfully requested that the International Preliminary Examination Report be established in accordance therewith.

Dated this 13th day of October, 1999.

Respectfully submitted,



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